DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

5155

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

Via Federal Express

Our Reference: 2954812

February 5, 2001

Rick L. Gorzeman
Cornerstone Dairy
8769 Avenue 128
Tipton, California 93272

WARNING LETTER

Dear Mr. Gorzeman:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on January 3, 2001 by the Food and Drug Administration (FDA) have revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act).

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512. On September 29, 2000, you consigned a cow, identified with back tag number 93 EZ 9696 (USDA laboratory report number 419133), for slaughter as human food. USDA analysis of tissue samples collected from that animal identified the presence of the drug oxytetracycline in the liver at 10.89 parts per million (ppm), in the muscle at 10.32 ppm, and in the kidney at 87.13 ppm, and gentamicin in the kidney at 00.46 ppm. Typically, USDA reports residues of all tetracyclines, including tetracycline, as oxytetracycline. A tolerance has not been established for residues of tetracycline, oxytetracycline and gentamicin in the edible tissues of lactating dairy cattle. Your use of tetracycline in a lactating dairy cow resulted in the illegal drug residue found in the liver, muscle, and kidney.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigator noted the following:

1. You lack an adequate system for determining the medication status of animals you offer for slaughter. Your medication records do not contain the dosage administered and the individual performing the medication of each animal at your dairy.

2. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.

3. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling or your veterinarian's prescription labeling.

4. You lack an adequate system for assuring animals have been treated only with drugs which have been approved for use in their class of animal or species.

The drug Polyotic brand of tetracycline soluble powder that your establishment uses on lactating dairy cows is adulterated under Section 501(a)(5) of the Act in that it is a new animal drug within the meaning of Section 201(v) and is unsafe within the meaning of Section 512(a)(1)(B) of the Act since it is not being used in conformance with its approved labeling. Your practice of filling a number 7 size gelatin capsule Polyotic brand tetracycline and inserting the filled capsule into the uterus of a lactating dairy cow for the treatment of retained placenta is an unapproved use for which safety and efficacy have not been proven. This constitutes manufacturing a new animal drug, which requires the submission of a New Animal Drug Application for FDA approval.

Your use of Biosol brand neomycin sulfate is not in accordance with approved labeling. Labeling for Biosol specifically states it is not to be used to treat female dairy cattle older than twenty months of age. The use of neomycin to treat lactating cows will likely cause illegal residues in animals you consign for slaughter.

Failure to comply with the label instructions on drugs you use to treat your cows and calves presents the likely possibility that illegal residues will occur and makes the drugs unsafe for use. We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act. Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale to a slaughter facility where it

was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

You should notify this office in writing, within fifteen (15) working days of the receipt of this letter, of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Russell A. Campbell, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, CA 94502.

Sincerely yours,

Dennis K. Linsley
District Director

cc: [redacted]